June 21, 2024

AgileMD, Inc.
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street
23rd Floor
Philadelphia, Pennsylvania 19103

Re: K233253
Trade/Device Name: eCARTv5 Clinical Deterioration Suite ("eCART")
Regulation Number: 21 CFR 870.2210
Regulation Name: Adjunctive Predictive Cardiovascular Indicator
Regulatory Class: Class II
Product Code: QNL
Dated: May 17, 2024
Received: May 17, 2024

Dear Kelliann Payne:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director

Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below

510(k) Number *(if known)*

K233253

Device Name

eCART

Indications for Use *(Describe)*

eCART is a software product that provides automated risk stratification and early warning for impending patient deterioration, signified as the composite outcome of death or ICU transfer. It is intended to be used on hospitalized ward patients 18 years of age or older by trained medical professionals.

As a clinical decision support device, eCART's risk score and trend analysis is intended to aid clinical teams in identifying which patients are most likely to clinically deteriorate. eCART provides additional information and does not replace the standard of care or clinical judgment.

eCART scoring is initiated by the documentation of any vital sign on an adult ward patient. The device calculates risk only from validated EHR data, such as vitals that have been confirmed by a registered nurse (RN); unvalidated data streaming from monitors/devices will not be used until confirmed by a healthcare professional. The product predictions are for reference only and no therapeutic decisions should be made based solely on the eCART scores.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

eCARTv5 Clinical Deterioration Suite

Submitter

AgileMD, Inc.
2261 Market Street #4378
San Francisco CA, 94114
Phone: 415-650-0522
Contact Person: Borna Safabakhsh

Date Prepared: June 20, 2024

Name of Device: eCARTv5 Clinical Deterioration Suite ("eCART")

Common or Usual Name: Clinical Monitor

Classification Regulation: 21 CFR 870.2210 (Adjunctive Predictive Cardiovascular Indicator)

Regulatory Class: II

Product Code: QNL

Predicate Device: CLEWICU (K200717)

Reference Device: PeraServer and PeraTrend (K172959)

Device Description

The AgileMD eCARTv5 Clinical Deterioration Suite ("eCART") is a cloud-based software device that is integrated into the electronic health record ("EHR") in order to anticipate clinical deterioration in adult ward patients, which is signified as either of the following two predicted outcomes: (1) death or (2) ICU transfer. The tool synthesizes routine vital signs, laboratory data, and patient demographics into a single value that can be used to flag patients at-risk of the composite outcome of clinical deterioration for additional evaluation and monitoring. eCARTv5 requires the healthcare system within which it will be used, to provide an EHR connection and data interfaces through which the patient data necessary to run the software will be transmitted.

The primary functions of the system are imparted by the Gradient Boosted Machine ("GBM") learning algorithm that takes input directly from the EHR, in real time, to provide an assessment of patients and displays its outputs in an intuitive user interface which drives providers to follow standardized clinical workflows (established by their institutions) for elevated-risk patients.

eCARTv5's end users include med-surg nursing staff, physicians and other providers caring for these patients. The eCARTv5 composite score is determined from the model output (predicted probability of deterioration) scaled from 0-100, based on the specificity (true negative rate). The observed rate of deterioration at each eCART score threshold, displayed as the odds of deterioration in the next 24 hours, is presented to the user along with the scaled score. Default thresholds are set to an eCART of 93 and 97, respectively, for moderate and high risk categorization.

Intended Use / Indications for Use

eCART is a software product that provides automated risk stratification and early warning for impending patient deterioration, signified as the composite outcome of death or ICU transfer. It is intended to be used on hospitalized ward patients 18 years of age or older by trained medical professionals.

As a clinical decision support device, eCART's risk score and trend analysis is intended to aid clinical teams in identifying which patients are most likely to clinically deteriorate. eCART provides additional information and does not replace the standard of care or clinical judgment.

eCART scoring is initiated by the documentation of any vital sign on an adult ward patient. The device calculates risk only from validated EHR data, such as vitals that have been confirmed by a registered nurse (RN); unvalidated data streaming from monitors/devices will not be used until confirmed by a healthcare professional. The product predictions are for reference only and no therapeutic decisions should be made based solely on the eCART scores.

The differences in indications for use from the predicate device are not critical to the intended use of eCARTv5, nor do they raise different questions of safety or effectiveness when the subject device is used as labeled. The minor differences are supported by adequate performance testing that show the subject device is substantially equivalent for the proposed indications for use. Both devices are intended to provide trained healthcare providers with a patient status score that reflects the underlying patient condition to supplement standard of care and informed decision making.

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements:

- A risk-predictive output generated using a machine-learning algorithm.
- Inputs to the software device include vital signs, assessments, and laboratory data collected from the hospital EHR system.
- The output is a color-defined (red-yellow), real-time risk categorization to provide users information regarding potential risk of patient deterioration.
- Embedded workflow features enable users to acknowledge the risk prediction and record next steps for medical management, based on their independent medical judgment.

The primary technological differences between the devices are that eCART's algorithm was trained on ward patients to predict the probability of ICU transfer or death, whereas the predicate is trained in ICU patients to predict respiratory failure and/or hemodynamic instability. Additionally, the predicate device does not provide a risk score (but rather, a risk category). The minor technological differences between the devices raise no different questions of safety or effectiveness. With respect to the output, the reference device (PeraServer and PeraTrend (K172959) provides a risk score (the Rothman Index), which was validated on the outcome of mortality within 24 hours and included training and testing on data from adult ward patients (similar to eCART). Performance data for eCART, including retrospective and prospective clinical testing as well as human factors validation, demonstrates that the subject device is substantially equivalent to the predicate device.

Performance Data

eCART was assessed in retrospective and prospective validation studies with adult ward patients from three geographically distinct health systems. Test characteristics for both cohorts are shown in

Table A below. The retrospective analysis included admissions between 2009 and 2023 in three health systems. Deterioration is defined as death or ward to ICU transfer within 24 hours following a score. The mortality outcome is defined as death within 24 hours following a score. The prospective validation was performed in the same three healthcare systems where the retrospective analysis was undertaken. This analysis included non-overlapping admissions between 2023 and 2024.

Encounters (N) are defined as unique hospitalizations for a single patient. Some patients may have more than one encounter in the data set if they were admitted and discharged from a study hospital more than once during the study period. Each encounter includes all eCART scores (observations, n) generated during that hospitalization.

Table A. eCART Prediction of Deterioration and Mortality in the Full External Retrospective and Prospective Cohorts

		DETERIORATION		MORTALITY	
		Retrospective N=1,769,461	**Prospective** N=205,946	**Retrospective** N=1,769,461	**Prospective** N=205,946
AUROC		0.835 (0.834, 0.835) n=132,873,833	0.828 (0.827, 0.829) n=21,516,964	0.923 (0.923, 0.924) n=132,873,833	0.913 (0.911, 0.914) n=21,516,964
Outcome Prevalence		1.3% 1,744,044/132,873,833	1.3% 284,678/21,516,964	0.2% 249,636/132,873,833	0.2% 39,609/21,516,964
Moderate-risk threshold eCART≥93	**Positivity Rate**	7.5% 9,982,577/132,873,833	7.3% 1,563,648/21,516,964	7.5% 9,982,577/132,873,833	7.3% 1,563,648/21,516,964
	Sensitivity	51.8% (51.7%, 51.8%) 902,951/1,744,044	48.8% (48.7%, 49.0%) 139,043/284,678	75.8% (75.6%, 75.9%) 189,171/249,636	71.7% (71.3%, 72.1%) 28,399/39,609
	Specificity	93.1% (93.1%, 93.1%) 122,050,163/131,129,789	93.3% (93.3%, 93.3%) 19,807,681/21,232,286	92.6% (92.6%, 92.6%) 122,830,791/132,624,197	92.9% (92.8%, 92.9%) 19,942,106/21,477,355
	PPV	9.0% (9.0%, 9.1%) 902,951/9,982,577	8.9% (8.8%, 8.9%) 139,043/1,563,648	1.9% (1.9%, 1.9%) 189,171/9,982,577	1.8% (1.8%, 1.8%) 28,399/1,563,648
	NPV	99.3% (99.3%, 99.3%) 122,050,163/122,891,256	99.3% (99.3%, 99.3%) 19,807,681/19,953,316	100.0% (100.0%, 100.0%) 122,830,791/122,891,256	99.9% (99.9%, 99.9%) 19,942,106/19,953,316
	Risk Diff	8.4% (8.3%, 8.4%)	8.2% (8.1%, 8.2%)	1.8% (1.8%, 1.9%)	1.8% (1.7%, 1.8%)
High-risk threshold eCART≥97	**Positivity Rate**	3.6% 4,753,332/132,873,833	3.1% 675,279/21,516964	3.6% 4,753,332/132,873,833	3.1% 675,279/21,516964
	Sensitivity	38.6% (38.5%, 38.7%) 673,539/1,744,044	33.7% (33.6%, 33.9%) 96,051/284,678	64.7% (64.5%, 64.9%) 161,531/249,636	58.1% (57.6%, 58.6%) 23,025/39,609
	Specificity	96.9% (96.9%, 96.9%) 127,049,996/131,129,789	97.3% (97.3%, 97.3%) 20,653,058/21,232,286	96.5% (96.5%, 96.5%) 128,032,396/132,624,197	97.0% (97.0%, 97.0%) 20,825,101/21,477,355
	PPV	14.2% (14.1%, 14.2%) 673,539/4,753,332	14.2% (14.1%, 14.3%) 96,051/675,279	3.4% (3.4%, 3.4%) 161,531/4,753,332	3.4% (3.4%, 3.5%) 23,025/675,279
	NPV	99.2% (99.2%, 99.2%) 127,049,996/128,120,501	99.1% (99.1%, 99.1%) 20,653,058/20,841,685	99.2% (99.2%, 99.2%) 127,049,996/128,120,501	99.9% (99.9%, 99.9%) 20,825,101/20,841,685
	Risk Diff	13.3% (13.3%, 13.4%)	13.3% (13.2%, 13.4%)	3.3% (3.3%, 3.3%)	3.3% (3.3%, 3.4%)

Note: The encounter and observation data above represents 934,454 and 151,233 unique patients in the retrospective and prospective cohorts, respectively. 95% confidence intervals were calculated using the Clopper-Pearson method.

Subgroup analyses for select comorbidities are presented in Tables B-C below for deterioration and mortality, respectively, and show comparable performance across conditions. Sequencing data for the SARS-CoV-2 variants included in the COVID subgroup analyses was not available, but the sample likely included the common variants circulating in the US between 2020 and the early part of 2024 (see https://cov-lineages.org/lineage_list.html). The comparative effectiveness of the model between existing SARS-CoV-2 strains or to future strains is unknown.

Table B. eCART Prediction of Clinical Deterioration in Select Comorbidities in the Full External Retrospective Cohort

DETERIORATION		Comorbidity			
		Congestive Heart Failure N = 306,140	COVID-19 N = 49,834	Chronic Pulmonary Disease N = 443,263	Sepsis N = 639,802
AUROC		0.810 (0.809, 0.810) n = 31,445,409	0.858 (0.857, 0.859) n = 5,961,084	0.824 (0.823, 0.824) n = 38,638,180	0.836 (0.836, 0.836) n = 72,055,421
Outcome Prevalence		2.2% 695,781/31,445,409	2.3% 136,077/5,961,084	1.7% 646,095/38,638,180	1.8% 1,295,361/72,055,421
Moderate-risk threshold (≥93)	Sensitivity	53.9% (53.8%, 54.1%) 375,328/695,781	69.6% (69.4%, 69.9%) 94,726/136,077	53.9% (53.8%, 54.0%) 348,271/646,095	56.4% (56.3%, 56.5%) 730,846/1,295,361
	Specificity	89.8% (89.7%, 89.8%) 27,600,037/30,749,628	84.6% (84.6%, 84.7%) 4,929,294/5,825,007	91.1% (91.0%, 91.1%) 34,593,348/37,992,085	90.8% (90.8%, 90.8%) 64,243,126/70,760,060
	PPV	10.6% (10.6%, 10.7%) 375,328/3,524,919	9.6% (9.5%, 9.6%) 94,726/990,439	9.3% (9.3%, 9.3%) 348,271/3,747,008	10.1% (10.1%, 10.1%) 730,846/7,247,780
	NPV	98.9% (98.8%, 98.9%) 27,600,037/27,920,490	99.2% (99.2%, 99.2%) 4,929,294/4,970,645	99.1% (99.1%, 99.1%) 34,593,348/34,891,172	99.1% (99.1%, 99.1%) 64,243,126/64,807,641
High-risk threshold (≥97)	Sensitivity	40.2% (40.1%, 40.3%) 279,748/695,781	55.9% (55.6%, 56.2%) 76,086/136,077	40.1% (40.0%, 40.3%) 259,354/646,095	42.6% (42.6%, 42.7%) 552,417/1,295,361
	Specificity	95.2% (95.1%, 95.2%) 29,259,307/30,749,628	90.7% (90.6%, 90.7%) 5,280,458/5,825,007	95.8% (95.8%, 95.9%) 36,413,561/37,992,085	95.6% (95.6%, 95.6%) 67,648,075/70,760,060
	PPV	15.8% (15.8%, 15.9%) 279,748/1,770,069	12.3% (12.2%, 12.3%) 76,086/620,635	14.1% (14.1%, 14.2%) 259,354/1,837,878	15.1% (15.%, 15.1%) 552,417/3,664,402
	NPV	98.6% (98.6%, 98.6%) 29,259,307/29,675,340	98.9% (98.9%, 98.9%) 5,280,458/5,340,449	98.9% (98.9%, 99.0%) 36,413,561/36,800,302	98.9% (98.9%, 98.9%) 67,648,075/68,391,019

Note: The encounter and observation data above represents 136,197 unique patients with congestive heart failure, 44,823 with COVID-19, 214,231 with chronic obstructive pulmonary disease, and 385,997 with sepsis. 95% confidence intervals were calculated using the Clopper-Pearson method.

Table C. eCART Prediction of Mortality in Select Comorbidities in the Full External Retrospective Cohort

MORTALITY		Comorbidity			
		Congestive Heart Failure N = 306,140	COVID-19 N = 49,834	Chronic Pulmonary Disease N = 443,263	Sepsis N = 639,802
AUROC		0.893 (0.892, 0.894) n = 31,445,409	0.924 (0.923, 0.926) n = 5,961,084	0.912 (0.911, 0.913) n = 38,638,180	0.914 (0.914, 0.915) n = 72,055,421
Outcome Prevalence		0.3% 103,194/31,445,09	0.5% 30,714/5,961,084	0.2% 85,582/38,638,180	0.2% 160,348/72,055,421
Moderate-risk threshold (≥93)	Sensitivity	73.6% (73.3%, 73.9%) 75,961/103,194	86.7% (86.3%, 87.1%) 26,639/30,714	76.1% (75.8%, 76.4%) 65,111/85,582	77.% (76.8%, 77.2%) 123,467/160,348
	Specificity	89.0% (89.0%, 89.0%) 27,893,257/31,342,215	83.7% (83.7%, 83.8%) 4,966,570/5,930,370	90.4% (90.4%, 90.5%) 34,870,701/38,552,598	90.1% (90.1%, 90.1%) 64,770,760/71,895,073
	PPV	2.2% (2.1%, 2.2%) 75,961/3,524,919	2.7% (2.7%, 2.7%) 26,639/990,439	1.7% (1.7%, 1.8%) 65,111/3,747,008	1.7% (1.7%, 1.7%) 123,467/7,247,780
	NPV	99.9% (99.9%, 99.9%) 27,893,257/27,920,490	99.9% (99.9%, 99.9%) 4,966,570/4,970,645	99.9% (99.9%, 99.9%) 34,870,701/34,891,172	99.9% (99.9%, 99.9%) 64,770,760/64,807,641
High-risk threshold (≥97)	Sensitivity	61.7% (61.4%, 62.0%) 63,697/103,194	79.2% (78.7%, 79.6%) 24,315/30,714	64.9% (64.5%, 65.2%) 55,507/85,582	66.1% (65.8%, 66.3%) 105,915/160,348
	Specificity	94.6% (94.5%, 94.6%) 29,635,843/31,342,215	89.9% (89.9%, 90.0%) 5,334,050/5,930,370	95.4% (95.4%, 95.4%) 36,770,227/38,552,598	95.1% (95.%, 95.1%) 68,336,586/71,895,073
	PPV	3.6% (3.6%, 3.6%) 63,697/1,770,069	3.9% (3.9%, 4.0%) 24,315/620,635	3.0% (3.0%, 3.0%) 55,507/1,837,878	2.9% (2.9%, 2.9%) 105,915/3,664,402
	NPV	99.9% (99.9%, 99.9%) 29,635,843/29,675,340	99.9% (99.9%, 99.9%) 5,334,050/5,340,449	99.9% (99.9%, 99.9%) 36,770,227/36,800,302	99.9% (99.9%, 99.9%) 68,336,586/68,391,019

Note: The encounter and observation data above represents 136,197 unique patients with congestive heart failure, 44,823 with COVID-19, 214,231 with chronic obstructive pulmonary disease, and 385,997 with sepsis. 95% confidence intervals were calculated using the Clopper-Pearson method.

Subgroup analyses for race are presented in **Table D**, below, for deterioration. All five groups met the performance thresholds for AUROC and sensitivity.

Table D. eCART Retrospective Validation Test Characteristics for the Outcomes of Clinical Deterioration by Race

DETERIORATION `		Race				
		American Indian or Alaska Native N = 6,468	**Asian/Mideast Indian** N = 26,681	**Black/African-American** N = 252,982	**Native Hawaiian/Other Pacific Islander** N = 2,496	**White/Caucasian** N = 1,384,075
AUROC		0.814 (0.808, 0.820) 486,615	0.847 (0.844, 0.850) 1,694,681	0.831 (0.830, 0.832) 20,057,696	0.862 (0.854, 0.870) 177,513	0.834 (0.833, 0.834) 104,522,118
Outcome Prevalence		1.2% 6,026/486,615	1.2% 20,736/1,694,681	1.2% 234,979/20,057,696	1.3% 2,395/177,513	1.3% 1,403,867/104,522,118
Moderate-risk threshold (≥93)	**Pos Rate**	6.7% 32,455/486,615	7.2% 121,532/1,694,681	6.5% 1,301,626/20,057,696	7.2% 12,738/177,513	7.7% 8,085,868/104,522,118
	Sensitivity	46.6% (45.3%, 47.9%) 2,809/6,026	52.9% (52.2%, 53.6%) 10,968/20,736	48.1% (47.9%, 48.3%) 112,939/234,979	56.5% (54.5%, 58.5%) 1,353/2,395	52.3% (52.2%, 52.3%) 733,566/1,403,867
	Specificity	93.8% (93.8%, 93.9%) 450,943/480,589	93.4% (93.4%, 93.4%) 1,563,381/1,673,945	94.0% (94.0%, 94.0%) 18,634,030/19,822,717	93.5% (93.4%, 93.6%) 163,733/175,118	92.9% (92.9%, 92.9%) 95,765,949/103,118,251
	PPV	8.7% (8.4%, 9.0%) 2,809/32,455	9.0% (8.9%, 9.2%) 10,968/121,532	8.7% (8.6%, 8.7%) 112,939/1,301,626	10.6% (10.1%, 11.2%) 1,353/12,738	9.1% (9.1%, 9.1%) 733,566/8,085,868
	NPV	99.3% (99.3%, 99.3%) 450,943/454,160	99.4% (99.4%, 99.4%) 1,563,381/1,573,149	99.3% (99.3%, 99.4%) 18,634,030/18,756,070	99.4% (99.3%, 99.4%) 163,733/164,775	99.3% (99.3%, 99.3%) 95,765,949/96,436,250
	Risk Diff	7.9% (7.6%, 8.3%)	8.4% (8.2%, 8.6%)	8.0% (8.0%, 8.1%)	10.0% (9.5%, 10.5%)	8.4% (8.4%, 8.4%)
High-risk threshold (≥97)	**Pos Rate**	3.1% 14,933/486,615	3.6% 60,178/1,694,681	3.1% 611,210/20,057,696	3.5% 6,174/177,513	3.7% 3,831,413/104,522,118
	Sensitivity	35.2% (34.0%, 36.4%) 2,122/6,026	40.9% (40.3%, 41.6%) 8,491/20,736	34.9% (34.7%, 35.1%) 81,982/234,979	40.0% (38.0%, 42.0%) 957/2,395	39.1% (39.0%, 39.1%) 548,404/1,403,867
	Specificity	97.3% (97.3%, 97.4%) 467,778/480,589	96.9% (96.9%, 96.9%) 1,622,258/1,673,945	97.3% (97.3%, 97.3%) 19,293,489/19,822,717	97.0% (96.9%, 97.1%) 169,901/175,118	96.8% (96.8%, 96.8%) 99,835,242/103,118,251
	PPV	14.2% (13.7%, 14.8%) 2,122/14,933	14.1% (13.8%, 14.4%) 8,491/60,178	13.4% (13.3%, 13.5%) 81,982/611,210	15.5% (14.6%, 16.4%) 957/6,174	14.3% (14.3%, 14.3%) 548,404/3,831,413
	NPV	99.2% (99.1%, 99.2%) 467,778/471,682	99.3% (99.2%, 99.3%) 1,622,258/1,634,503	99.2% (99.2%, 99.2%) 19,293,489/19,446,486	99.2% (99.1%, 99.2%) 169,901/171,339	99.2% (99.1%, 99.2%) 99,835,242/100,690,705
	Risk Diff	13.4% (12.8%, 13.9%)	13.4% (13.1%, 13.6%)	12.6% (12.5%, 12.7%)	14.7% (13.8%, 15.6%)	13.5% (13.4%, 13.5%)

Note: The encounter and observation data above represents 3,282 unique American Indian or Alaska Native patients, 17,657 Asian/Mideast Asian patients, 116,642 Black/African-American patients, 1,427 Native Hawaiian/Other Pacific Islander patients, and 735,514 White/Caucasian patients. 95% confidence intervals were calculated using the Clopper-Pearson method.

Conclusion

eCARTv5 has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device, CLEWICU. The minor differences in indications for use do not alter the intended fundamental clinical purpose of the device, nor affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between eCARTv5 and its predicate device raise no different questions of safety or effectiveness and are further supported by performance data. Thus, the device is substantially equivalent.